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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,458	05/25/2001	Gary G. Meadows	618.002US1	4123

21186 7590 07/15/2003

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EXAMINER
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GOLDBERG, JEROME D

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 07/15/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/866,458

Applicant(s)

MEADOWS ET AL.

Examiner

Jerome D Goldberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 April 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 4-34 is/are pending in the application.
- 4a) Of the above claim(s) 5-7 and 21-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,8-14,16-18 and 31-33 is/are rejected.
- 7) ☒ Claim(s) 15,19,20 and 34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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This application contains claims 5-7 and 21-30 are drawn to an invention nonelected with traverse in Paper No. 5. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicants are now required to cancel the non-elected claim and non-elected subject matter from the other claims.

Claims 1, 4, 8-20 and 31-34 are still being examined as they read on the elected invention.

Applicant is advised that should claim 1 be found allowable, claim 33 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The finality of the office action of October 10, 2002 is herein withdrawn in view of the Abdul et al. reference.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 8-14, 16-18 and 31-33 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the Abdul et al. reference.

The instant application has an effective date of May 28, 2000 while the Abdul et al. reference has an effective date of July, 1996. The Abdul et al reference teaches that the "growth of subcutaneous, PC-3 xenografts in athymic nude mice was significantly inhibited by fluoxetine" (abstract, page 247, lines 8 and 9) and the "PC-3 cell line was used to evaluate the effect of fluoxetine on the growth of prostate carcinoma cells in vivo in immunodeficient mice" (page 248, col.2, lines 3-5 after fig.1) accordingly, one skilled in this art would find ample motivation from the prior art supra to employ the claimed fluoxetine against cancers or tumors with a reasonable expectation that said

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compound would be effective to combat said cancers or tumors in a mammal including humans.

Claims 1, 8-14, 16-18, and 31-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific tumors or cancers disclosed, does not reasonably provide enablement for the term "tumor" or "cancer". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The term "cancer" in claims 1, 8-13 and 33; "cancer cells" in claims 14 and 16-18; "tumor" in claim 31 and "metastatic cancer" in claim 32 lack clear exemplary support in the specification as filed.

Enablement is considered in view of the Wands factors (MPEP 2164.01

(a). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary all of the wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: claims 1, 8-14, 16-18, 31, 32 and 3 are drawn to treating cancers or tumors broadly with fluoxetine in a mammal.

Breadth of the claims: the complex nature of the claim greatly exacerbated by breadth of the claims. The claims encompass treating cancers broadly in a mammal including humans.

Guidance of the specification:

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The guidance given by the specification as to how one would administer the claimed compounds to a subject in order to treating neoplasms broadly. The guidance provide by the specification is directed to specific cancer in a specific concentration of the claimed compounds.

Working examples; all the working examples provided by the specification are directed to specific cancers.

State of the art: while the state of the art is relatively high with regard to treatment of specific cancers, the state of the art with regard to single agent for treating cancers or tumors broadly is underdeveloped. In particular, there is no known anticancer agent which is effective against all cancers. The Carter et al reference clearly teaches that for the forty known anticancer agents, none are effective against all cancers. (see pages 362-365 of Carter et al reference).

Predictability of the art: the lack of significant guidance from the specification or prior art with regard to the actual treatment of all cancers or tumors in a mammal including humans subject with the claimed compounds makes practicing the claimed invention unpredictable.

The quantity of experimentation necessary:

Applicants fail to provide guidance and information to allow the skilled artisan to ascertain which particular type of cancer the claimed anticancer agent is effective against without undue experimentation. The limited disclosure of several cancer is noted but will not support all cancers being claimed. The Carter et al reference shows

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data on twenty-three types of cancer. Applicants should at least test these types of cancer with the claimed anticancer agent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner J. D. Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday through Thursday from 9:00 A.M - 3:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for this Group are (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Goldberg/tgd  
June 30, 2003



JEROME D. GOLDBERG  
PRIMARY EXAMINER